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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/006,800 | 12/04/2001 | Eija Pirhonen | 01942-00008 | 9838 |

22910 7590 05/07/2003

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BOSTON, MA 02109

EXAMINER

AZPURU, CARLOS A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

DATE MAILED: 05/07/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,800

Applicant(s)

Pirhonen et al

Examiner

Carlos Azpuru

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, and 9-11 is/are rejected.
- 7) ☒ Claim(s) 4 and 8 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other:

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DETAILED ACTION

Receipt is acknowledged of the information disclosure statement filed 03/20/03.

Applicant is requested to forward a copy of the claims in copending US Application No. 10/006,796 in order to review them for double patenting issues.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7, 9-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tipton et al.

Tipton et al disclose a biodegradable composition comprising a biodegradable polymer mixed in N-methyl pyrrolidone (see abstract). Biodegradable polymers used in the composition are listed at col. 5, lines 15-31. The composition may be used internally or externally, with bone healing specifically recited at col. 13, line 23. Even so, osteogenic properties of the composition are merely an intended use, and do not have patentable weight on the composition claims. (A composition is a composition.) The method of making is disclosed at col 12-13, and includes mixing of the biodegradable

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polymers and n-methylpyrrolidone (see examples 1-10). The addition of the NMP can be accomplished before or after the dispensing step which corresponds to pre and post operative addition (see claim 11). The instant claims are clearly anticipated by Tipton et al.

Claims 4 and 8 are objected to as dependent upon the rejected base claim.

It is therefore suggested that the limitations of these claims be added to the independent claims in order to place the claims in composition for allowance:

Martin et al and Valentini et al are cited as patents of interest in their disclosures which include bioabsorbable polymers and N-methylpyrrolidone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

ca
May 5, 2003



CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500